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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/772,185 | 02/04/2004 | Jude S. Sauer | LS-006CV | 4686 |
| 7590 Kenneth J. LuKacher, Esq. South Winton Court Suite 204 3136 Winton Road South Rochester, NY 14623 | | | | |
| | | | EXAMINER NGUYEN, VI X | |
| | | | ART UNIT 3734 | PAPER NUMBER |
| | | | MAIL DATE 02/13/2009 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/772,185

Applicant(s)

SAUER, JUDE S.

Examiner

Victor X. Nguyen

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15-18 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-18 and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The request filed on 11/12/2008 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/772,185 is acceptable and a RCE has been established. An action on the RCE follows.
2. Claims 1-10,15-18 and 20-27 are pending in this present application.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,10,16,18 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Shelden 2,873,742.

Shelden discloses in figures 6-8, a device is used to cut tissue having the limitations as recited in the above listed claim, including: a shaft 43 extends from a housing to a distal end of the instrument, where the shaft has an opening at the distal end to out side of the instrument (see fig. 6), a guide tube 37 extends from the shaft through the opening, where a path is through the guide tube for extending a guidewire, where means for longitudinally cutting tissue along a path defined by the guide tube, the means comprising a blade 38 extendable and retractable through the opening of the shaft to cut tissue out side of the instrument, where the guide tube extends through the opening of the shaft beyond the distal end of the blade, when retracted to define a path along which the blade is extendable and retractable at best seen in fig.6, where the shaft is at least partially flexible so the tube can be inserted within the trachea, where the guide tube is

stationary with the shaft, and where the blade has a sharp edge (element 38, fig. 8) to allow the edge of the blade to cut tissue. As to claims 25-27, it is noted that a blade 38 at a distal end of a shaft 43 that is movable to extend out of the shaft to cut tissue when present out side of the instrument, a guide member 37 which guide movement of the blade at the distal end out of the shaft, where the shaft 43 has an opening to out side of the instrument and the blade 38 extends out of the shaft through the opening to cut tissue outside of the instrument which neighbors the guide member 37.

Claims 1-4,6-10,15-18 and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Spaulding 6,036,707.

Spaulding discloses in figures 5-6, a device is used to cut tissue having the limitations as recited in the above listed claim, including: a shaft 32 extends from a housing to a distal end of the instrument, where the shaft has an opening at the distal end to out side of the instrument (see fig.5), a guide tube (the area between element 42 to distal end of element 53) extends from the shaft through the opening, where a path is through the guide tube for extending a guidewire, where means for longitudinally cutting tissue along a path defined by the guide tube, the means comprising a blade or a cutter 60 extendable and retractable through the opening of the shaft to cut tissue out side of the instrument, where the guide tube extends through the opening of the shaft beyond the distal end of the blade, when retracted to define a path along which the blade is extendable and retractable at best seen in fig.6, where the shaft is at least partially flexible so the tube can be inserted within the blood vessel, where the guide tube is stationary with the shaft, and where the blade has a sharp edge (see col. 5, lines 46-50) to allow the edge of the blade to

cut tissue. As to claims 4, 8,9 and 22, note a movable blade shuttle 46 has a blade or a cutter 60 described in col. 5, lines 38-50 and col. 6, lines 14-22 of Spaulding.

As to claims 6, 15,17,21,22 and 26, note a guidewire 40 is extended along a path for extending the guidewire described in fig. 6 of Spaulding. As to claim 7, it is noted that the limitation "said shaft is extendable through an endoscope" (an intended use limitation): a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim (see MPEP 2106).

As to claims 25,27, it is noted that a blade or a cutter 60 at a distal end of a shaft 32 that is movable to extend out of the shaft to cut tissue when present out side of the instrument, a guide member (the area between element 42 to distal end of element 53) which guide movement of the blade at the distal end out of the shaft, where the shaft 32 has an opening to out side of the instrument and the blade 60 extends out of the shaft through the opening to cut tissue outside of the instrument which neighbors the guide member.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spaulding in view of Sauer et al 5,562,694.

Spaulding discloses the invention substantially as claims (see claims 1 and 8 above)

However, Spaulding is silent regarding a pivotal actuator member at the housing with one or more rods. Sauer et al disclose such a pivotal actuator member 118 at the housing with one or more rods 252,254 (figures 2-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Spaulding by making the device has a pivotal actuator member at the housing with one or more rods as taught by Sauer to allow prediction result of adding an additional actuator that would enhance the extension/retraction of the blade efficiently.

Response to Arguments

5. Applicant's amendment filed 11/12/2008 has been considered but is moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VN/

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734